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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/926,361 03/26/97 MOSELLEMAN

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EXAMINER

HM22/0517

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POK, M  
ART UNIT PAPER NUMBER

1646  
DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>08/826,361</b>	Applicant(s) <b>Moselman et al.</b>
	Examiner <b>Michael Pak</b>	Group Art Unit <b>1646</b>

Responsive to communication(s) filed on Apr 1, 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- Claim(s) 1-12 and 14-18 is/are pending in the application.
- Of the above, claim(s) 9-11, 14, and 18 is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) 1-8, 12, and 15-17 is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been
- received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \*Certified copies not received: \_\_\_\_\_
- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). 6 and 12
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

***Election/Restriction***

1. Applicant's election of Group I, claims 1-8, 12, and 15-17, in Paper No. 14 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

***Information Disclosure Statement***

2. The information disclosure statement (IDS) listed two references with the letter identification AJ and AO. WO97/09348A has been relabeled AK and Mosselman et al. has been relabeled AN.

***Claim Objections***

3. Claim 12 is objected to because of the following informalities.

Claim 12 is dependent on a non-elected claim.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-3, 6-8, 12, and 15-17 are indefinite because instructions or an algorithm for determining percent sequence identity is missing from the specification. Claims 1-3, 6-8, 12, and 15-17 use "identity" in terms of percentage. The specification fails to clearly set forth the algorithm and the parameters within the algorithm which would be necessary to do the percent identity calculations. The state of the art is such that one skilled in the art cannot determine what the meaning of the term "identity" is without a precise algorithm with parameters i.e. "scoring rules" (George et al. (V), page 130, right column, top paragraph, is cited as of interest to the applicant). For example, consider two hypothetical sequences acgtac and acac. These can be compared in any of four ways, yielding four different percent identity results.

acgtac      4/6 = 67%      acgtac      2/6 = 33%

—  
—  
—

ac--ac      4/4 = 100%      acac      2/4 = 50%

Thus, a specific definition of identity must be provided taking into considerations such variables as: complete vs partial sequence, gap distances, as well as other parameters of the algorithm.

**Claim Rejections - 35 USC § 102**

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1-8, and 15-17, are rejected under 35 U.S.C. 102(e) as being anticipated by Kausch et al.((A); U.S. '164).

Kausch et al. disclose the isolation of human and mouse chromosome (column 5). The cell source are human and mouse cells (column 6, lines 5-15). Many chromosomes can be sorted at once (column 9, lines 29-43). Large amounts of pure chromosomes may be isolated(column 10, lines 22-25). The DNA from the chrcmosome is used for library construction and cloning, DNA uptake in to vectors and host cells, and transformation into host cells (column 10, lines 22-34).

Claims 1-5 and 15-16 encompass chromosomal DNA because the claims encompass nucleic acid comprising the nucleotide sequence encoding a human estrogen receptor beta. The isolated and purified chromosomal DNA comprise the polynucleotide sequence

encoding a human estrogen receptor beta. Claims 6-8 and 17 limitations are met because the chromosomal DNA is used for library construction and cloning, and DNA uptake into vectors and host cells, which is a vector comprising the DNA and the cell comprising the DNA.

7. Claims 1-3, 6-8, and 15-17, are rejected under 35 U.S.C. 102(a) as being anticipated by Karo Bio Ab ((AK); WO '348).

KARO BIO AB discloses the human DNA encoding the human estrogen receptor beta (figure 13) which has the identical sequence as the claimed human estrogen receptor beta DNA sequences. KARO BIO AB discloses the vector comprising the DNA encoding the human estrogen receptor beta and the cell comprising transfected with the vector.

Claims 1-3, 6-8, and 15-17 limitations encompass nucleic acid, vector, and cell of KARO BIO AB because the sequence limitations are drawn to "comprising" language and reference meet the limitations.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-3, 6-8, 12, and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karo Bio Ab ((AK); WO '348) in view of Evans et al.((B); U.S. '233).

The teaching of Karo Bio Ab is discussed above. Karo Bio Ab do not teach a DNA encoding a fusion protein.

Evans et al. teach DNA encoding fusion proteins of nuclear or steroid receptor family members and a method of screening for ligands using the chimeric receptors (column 7, lines 19 to column 8, line 31).

It would have been obvious to one of ordinary skill in the art at the time of the invention to make a DNA encoding a chimeric receptor by using the human estrogen receptor beta of Karo Bio Ab and the teachings of Evans et al. for making the chimeric receptor. One of ordinary skill in the art would have been motivated because of expressed interest of Karo Bio Ab understanding the mechanism of orphan receptors (page 2) and the interest in identifying ligands of the human estrogen receptor beta (page 3). Furthermore, Evans et al. complement the motivation of Karo Bio Ab because Evans et al. teach products and methods of using chimeric receptors for analyzing orphan receptors including estrogen receptors and estrogen related receptors (column 7, line 31-32).

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Mosselman et al. ((AN); FEBS Letters, 1996) and Kuiper et al.((AS); PNAS, 1996) are cumulative references with Karo Bio Ab ((AK); WO '348).

Lin et al.((U); Science, 1975) is a cumulative reference

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with Kausch et al. (A).

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MOP

Michael Pak  
Patent Examiner  
Art Unit 1646  
5 May 1999

  
PAULA K. HUTZELL  
SUPERVISORY PATENT EXAMINER